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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,591	07/10/2000	William J. Boyle	A-378CIP5	9711

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EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/613,591

Applicant(s)

BOYLE ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17-25,39-42 and 62-65 is/are pending in the application.
- 4a) Of the above claim(s) 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-25,39-42 and 62-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 27.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Status of Application, Amendments and/or Claims***

The amendment filed 02 October 2002 (Paper No. 28) has been entered in part. Claim 1 was cancelled. Claims 17-25, 39-42 and 62-65 are under examination.

The terminal disclaimer filed on 02 October 2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,288,032 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Applicant is to disregard the IDS statement regarding references filed 31 December 2001 (Paper No. 21).

Applicant states in the Supplemental Information Disclosure Statement that a copy of the prior Form 1449 and copy of the referenced submitted November 8, 200 (Paper No. 3) have been submitted. Unfortunately, the Examiner has only received the Form 1449. It is suggested that Applicant have the references had delivered to the Examiner.

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Objections And/Or Rejections***

The objection to the specification as set forth at page 3 of the previous Office Action (04 June 2002, Paper No. 25) is *withdrawn* in view of Applicant's argument filed in the amendment (02 October 2002, Paper No. 28).

The rejection of claim 24 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which

Applicant regards as the invention as set forth at page 6 of the previous Office Action (04 June 2002, Paper No. 25) is *withdrawn* in view of Applicant's argument and submission of the USP Dictionary of USAN and International Drug Names (for the term etanercept) filed in the amendment (02 October 2002, Paper No. 28).

The rejections of claims of claims 17, 25, 39, 41 and 42 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-14 of U.S. Patent No. 6,288,032B as set forth at pages 7-8 of the previous Office Action (04 June 2002, Paper No. 25) is *withdrawn* in view of the Terminal Disclaimer filed 02 October 2002 (Paper No. 28).

The rejections of claims of claims 18-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-14 of U.S. Patent No. 6,288,032B in view of Thompson *et al.* WO 93/21947 (IDS#B2, Paper No. 17) as set forth at pages 8-9 of the previous Office Action (04 June 2002, Paper No. 25) is *withdrawn* in view of the Terminal Disclaimer filed 02 October 2002 (Paper No. 28).

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The rejections of claims of claims 20-22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-14 of U.S. Patent No. 6,288,032B in view of Fisher *et al.* WO 98/01555 as set forth at page 9 of the previous Office Action (04 June 2002, Paper No. 25) is *withdrawn* in view of the Terminal Disclaimer filed 02 October 2002 (Paper No. 28).

The rejections of claims of claim 23 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-14 of U.S. Patent No. 6,288,032B in view of Murray *et al.* (abstract, Ann Pharmacother. 11:1335-8,

Nov. 31 1997) as set forth at page 10 of the previous Office Action (04 June 2002, Paper No. 25) is *withdrawn* in view of the Terminal Disclaimer filed 02 October 2002 (Paper No. 28).

The rejections of claims of claim 40 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-14 of U.S. Patent No. 6,288,032B in view of Miyagi *et al.* (abstract, Shinshu Igaku Zasshi 40/6:567-75, 1992) as set forth at page 10 of the previous Office Action (04 June 2002, Paper No. 25) is *withdrawn* in view of the Terminal Disclaimer filed 02 October 2002 (Paper No. 28).

#### **Withdrawn Claims**

Newly submitted claim 65 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 65 recites, "wherein the OPG protein comprises an antibody to OPG ligand". Applicant elected Group IV, claims drawn to a method for treating conditions leading to bone loss which comprises administering isolated OPG protein, IL-1 inhibitor and TNF- $\alpha$  inhibitor. Please see Election/Restriction 22 March 2002, Paper No. 24. Applicant's amendment adds a new limitation (antibody to OPG ligand).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 64 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### **Claim Objections**

Claim 17 is objected to because of the following informalities: Claim 17 encompasses a non-elected invention and requires amendment to limit to elected invention. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Appropriate correction is required.

Claims 18-25, 39-42, and 62-64 are objected to because of the following informalities: The instant claims depend on claims drawn to a non-elected group. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

### **Claim Rejections - 35 USC § 112, second paragraph**

Claims 17, 19, 21, 22, 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 19 are indefinite because of the recitation " a TNF- $\bullet\bullet$ inhibitor". It is unclear if this is a typo or if Applicant is claiming "a TNF- $\alpha$  inhibitor".

Claims 19, 21 and 22 are indefinite because of the interchangeable use of "sTNFR-I" and "sTNF-RI". The basis for this rejection is set forth at page 6 of the previous Office Action (04 June 2002, Paper No. 25). The amendment filed 02 October 2002 (Paper No. 28) does not overcome the rejection. The rejection was to the use of "sTNFR-I" and "sTNF-RI" NOT "sTNFR-II". The rejection is still maintained.

Claim 21 recites "wherein the sTNF-RI". There is insufficient antecedent basis for this limitation in the claim. The basis for this rejection is set forth at page 6 of the previous Office Action (04 June 2002, Paper No. 25). Claim 21 was not addressed in the amendment. The rejection is still maintained.

Claims 39-42 recite "wherein the condition". Claims 39-42 are indefinite because there is insufficient antecedent basis for this limitation in the claims.

Claims 17, 62-64 are indefinite because of the interchangeable use of SEQ ID Nos 123, 125, 171, 172 and 173. The Examiner understands the SEQ ID Nos to be:

SEQ ID NO:123 and SEQ ID NO:171, both drawn to the OPG amino acid sequence of mouse.

SEQ ID NO:125 and SEQ ID NO:173, both drawn to the OPG amino acid sequence of human

SEQ ID NO:172 drawn to the OPG amino acid sequence of rat.

It is unclear why the instant claims recites two sets of SEQ ID Nos drawn to the same species of OPG.

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### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

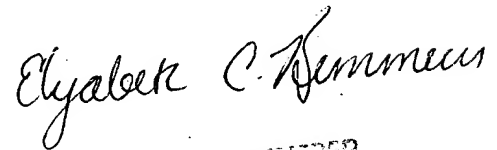
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



RMD

January 13, 2003



ELIZABETH C. HEMME  
REGISTERED  
PATENT EXAMINER